



### REMARKS

Applicants have carefully reviewed and considered the Office Action mailed on May 12, 2005, and the documents cited therewith.

No claim is amended, claims 4-13, 16-18, and 20-27 were canceled previously, and no claims are added; as a result, claims 1-3, 14, 15, 19, and 28-32 are now pending in this application. A clean set of the pending claims is included to facilitate discussion. It should be noted that claim 28 is still pending, but was neither accounted for on the form PTOL-326 accompanying the Office Action nor mentioned in the Office Action. Applicants presume this claim is allowable. Clarification is requested.

The specification has been amended to provide additional antecedent basis for the claimed embodiment wherein the thermoplastic polymer is in mixture with a non-polymeric material. No new matter has been added.

### Objection to Specification

The Examiner has objected to the specification under 37 C.F.R. § 1.75(d)(1) as failing to provide antecedent basis for the claimed embodiment wherein the thermoplastic polymer is in mixture with a non-polymeric material. Applicant pointed out in the previous response that descriptive support for such an embodiment was present in the Abstract. The Examiner apparently is requiring that support be inserted again elsewhere in the specification.

As Applicant noted in the previous response, the abstract of the disclosure is part of the specification for the purpose of compliance with 35 U.S.C. § 112, first paragraph. MPEP § 608.01(b)(citing *In re Armbruster*, 512 F.2d 676, 678-79, 185 USPQ 152, 154 (CCPA 1975)). As such, further amending should not be necessary. Nevertheless, Applicant has inserted additional descriptive support in the specification at page 9, second paragraph. No new matter has been added. Support for the change is present in the Abstract.

Withdrawal of this objection is respectfully requested.

### §102 Rejections of the Claims

Claims 1-3, 14-15, 19, and 29-32 were rejected under 35 USC § 102(b) as being anticipated by Yamamoto et al. (USP 4,954,298). The Examiner stated: "Yamamoto et al teach

a W/O emulsion composed of a water soluble drug containing solution as the inner aqueous phase and a polymer containing solution as the oil phase (abstract).” Office Action at page 2.

Claims 1-3, 14, 15, 19, and 29-32 were rejected under 35 USC § 102(b) as being anticipated by Okada et al. (USP 4,652,441). The Examiner stated: “Okada et al teach water-oil emulsions comprising a water soluble drug in the aqueous phase and a polymer in the oil phase (abstract).... An intended use is not considered a patentable limitation during prosecution before the USPTO.” Office Action at page 3.

The Examiner stated he cannot recall (presumably from the discussion at the personal interview of December 2, 2004) whether the last two lines of present claim 1 would or would not be an intended use. The Examiner went on to assume that the two lines *were* an intended use, and rejected the claims for being the same composition as in the cited documents. At page 4, the Examiner asked for further elaboration on this intended use issue. These rejections are respectfully traversed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). To constitute anticipation, the claimed subject matter must be identically disclosed in the prior art. *In re Arkley*, 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, “it is only necessary for the patentee to show some tangible difference between the invention and the prior art.” *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

As discussed at the personal interview with Applicant’s representative, Richard A. Schwartz, on December 2, 2004, and agreed to by the Examiner, the last two lines of present claim 1 recite a property or mode of operation of the controlled release formulation and not an intended use. When the controlled release formulation contacts an aqueous medium, such as water or body fluid, the matrix forming material coagulates or precipitates to form a solid

implant in which the biologically active mixture is entrapped. See specification at page 4, lines 25-28. Even a small amount of aqueous medium will begin the coagulation/precipitation. See specification at page 16, lines 1-5. It is this property or mode of operation that permits Applicant's formulation to be used to form an *in situ* solid implant for delivering a biologically active agent.

Moreover, it is this property or mode of operation of Applicant's formulation that distinguishes it from the emulsions of Yamamoto et al. and Okada et al. Applicant's formulation is not identical to the W/O emulsions of Yamamoto et al. and Okada et al. because if it were identical, it would solidify under the procedures used with the W/O emulsions by Yamamoto et al. and Okada et al.

In Yamamoto et al., the W/O emulsion is added to a third, aqueous phase and emulsified into a W/O/W triplicate-phase emulsion. The W/O/W emulsion is then subjected to in-water drying and solvent removal to produce microcapsules. Yamamoto et al. at column 6, lines 20-25. Since this W/O/W emulsion is not a solid, the W/O emulsion used to prepare it cannot be identical to Applicant's formulation because Applicant's formulation would solidify when added to an aqueous phase or subjected to in-water drying.

Similarly, the W/O emulsion of Okada et al. is also added to a third, aqueous layer and emulsified into a W/O/W ternary layer emulsion, which is then subjected to in-water drying and solvent removal to produce microcapsules. Okada et al. at column 7, lines 51-55. Since this W/O/W emulsion is not a solid, the W/O emulsion used to prepare it cannot be identical to Applicant's formulation because Applicant's formulation would solidify when added to an aqueous phase or subjected to in-water drying.

Therefore, because the claimed subject matter is not identically disclosed in Yamamoto et al. or Okada et al., there can be no anticipation. Withdrawal of this rejection is respectfully requested.

**AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111**

Serial Number: 09/060,047

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Title: EMULSIONS FOR IN-SITU DELIVERY SYSTEM

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Dkt: 1195.157US1**Conclusion**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (703) 239-9592 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

RICHARD L. DUNN

By his Representatives,

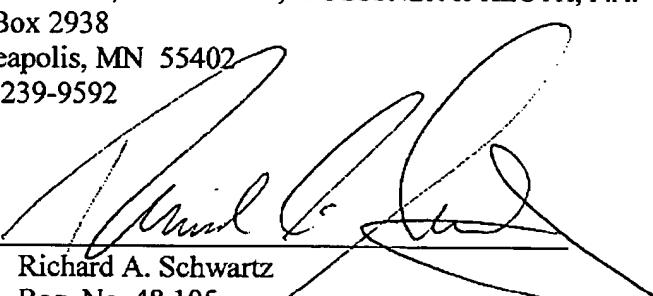
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May 25, 2005

By

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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 25 day of May, 2005.

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